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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,370	01/23/2001	Jeffrey Browning	BGNA054RCE	2716
959	7590	08/24/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/767,370

Applicant(s)

BROWNING ET AL.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10,11,16,26,28,29 and 37-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10,11,16,26,28,29 and 37-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ~~6/2/05~~ 5-31-05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

RE: Browning et al

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/31/2005 and 8/3/2005 has been entered.
2. Claims 1-7,9,12-15,,17-25,27, and 30-36 are canceled without prejudice or disclaimer, claims 49-51 are newly added.
3. Claims 8,10-11,16,26,28-29, and 37-51 are pending and examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed 5/31/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

New Arguments

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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6. Claims 8,26,39,42,43, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Beutler *et al* (US Patent 5,447,851, cited on IDS 5/31/2005) as evidenced by Invitrogen Life Technologies Instruction Manual (*BaculoDirect™ Baculovirus Expression System* 2004; Version F:1-64, herein Invitrogen manual). It is noted that for the purposes of this rejection the term "about 25°C" encompass the temperature of 27°C.

Beutler *et al* teach the production of a TNF receptor-Ig fusion or chimeric protein and indicate that the fusion protein can be prepared in eukaryotic cells such as CHO cells or insect cells (see col. 9, for example). Although Beutler *et al* do not specifically teach the temperature at which the cells producing the fusion protein are cultured, because insect cells and the baculovirus expression system are used, the temperature at which the cells are incubated would be at 27°C, as evidenced by the Invitrogen manual, and therefore the preparation taught by Beutler *et al* would produce at least 70% biologically active fusion protein and no more than 30% inactive protein. Thus, the claimed preparation appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 8,11,26,29,37,38-40,42-43, and 49 are rejected under 35 U.S.C. 102(a) as being anticipated by Ashkenazi *et al* (WO 98/25967, cited on IDS 5/31/2005) as evidenced by Invitrogen Life Technologies Instruction Manual (*BaculoDirectTM Baculovirus Expression System* 2004; Version F:1-64, herein Invitrogen manual). It is noted that for the purposes of this rejection the term “about 25°C” encompass the temperature of 27°C.

Ashkenazi *et al* teach a HVEM-Ig fusion protein (see page 4) preparation that can be purified to a homogeneous form (see page 19, for example). IT is also taught that the fusion protein can be prepared from various systems including CHO cells and baculovirus expression systems (see pages 10 and 14). Although Ashkenazi *et al* do not specifically teach the temperature at which the cells producing the fusion protein are cultured, because insect cells and the baculovirus expression system are used, the temperature at which the cells are incubated would be at 27°C, as evidenced by the Invitrogen manual, and therefore the preparation taught by Beutler *et al* would produce at least 70% biologically active fusion protein and no more than 30% inactive protein. Thus, the claimed preparation appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to

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establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 8,10,11,16,26,28-29, and 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowe *et al*, Kwon *et al*, or Rennert *et al* (all previously cited) in view of Nilsson *et al* (Protein Expr Purif. 1997 Oct;11(1):1-16) or Beutler *et al* (US Patent 5,447,851).

- a. The teachings of Crowe *et al*, Kwon *et al*, and Rennert *et al* have been previously set forth (see office actions mailed 8/13/2002, 5/20/2003, 5/25/2004, and 12/28, 2004).
- b. Crowe *et al*, Kwon *et al*, and Rennert *et al* however do not specifically teach a high yield preparation comprising at least 70% biologically active receptor-Ig fusion protein.
- c. Nilsson *et al* reviews methods of purifying fusion proteins, involving multiple purification techniques and further teaches that protein preparations can be purified to include homogeneous populations of proteins.
- d. Beutler *et al* teach the production of a TNF receptor-Ig fusion protein, wherein the fusion protein is produced in a baculovirus expression system.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a high yield preparation comprising an Ig-receptor fusion protein that consists of at least 70% active fusion protein. One of skill in the art would have been motivated to do so because Crowe *et al*, Kwon *et al*, and Rennert *et al* taught that the fusion proteins were active and that the fusion protein could be purified. Moreover, it was well known in the art at the time the invention was made that protein, especially fusion proteins, could be purified to high yield or to homogeneity so as to

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particularly isolate and or separate biologically active proteins from inactive forms. In addition, one of skill in the art would have had reasonable motivation in doing so because Beutler *et al* taught that the method used should be dictated by those that produce the most active polypeptide (see col. 9, in particular). One of skill would expect reasonable expectation of success in doing so because the art is replete with examples of purification procedures and thus the production of a high yield preparation with biologically active receptor-Ig fusion protein is obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
August 15, 2005


CHRISTOPHER YAEN
PATENT EXAMINER